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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,911	12/30/2004	Shinya Nagata	T3736-9303US01	2644

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EXAMINER
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DIETRICH, JOSEPH M

ART UNIT	PAPER NUMBER
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3709

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07/10/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/519,911

Applicant(s)

NAGATA ET AL.

Examiner

Joseph M. Dietrich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/6/05; 12/29/05; 4/6/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 100 (page 10, line 20). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. The disclosure is objected to because of the following informalities:

Page 11, line 31, the word "chart" is misspelled. Appropriate correction is required.

### ***Claim Objections***

3. Claims 9 – 10 are objected to because of the following informalities:

The word "comprises" should be inserted between the words "further" and "outputting" in line 2 of each claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 3, 7 – 9, 11 – 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by the English translation of Satoko Sato (Japanese Patent 6-205751).

The Japanese patent issued to Sato discloses an apparatus for recording and analyzing cardiac potential.

Regarding claims 1, 2, 11 and 12 Sato discloses an electrocardiogram (ECG) analysis device for analyzing an ECG (Sato, paragraph 6, lines 2 – 6), a computer readable medium having stored thereon the computer program for an ECG analysis device that analyzes an ECG (Sato, paragraph 7, lines 1 – 7), a method, and a means for: analyzing level of an ECG feature value (Sato, paragraph 8, lines 3 – 6); determining disease information relating to a patient's disease based on information including the feature value (Sato, paragraph 30, lines 1 – 5); and outputting both the feature value analysis result and the disease information result (Sato, paragraph 19, lines 2 – 4; paragraph 30, lines 1 – 5).

Regarding claim 3, Sato discloses the outputting means further displays a chart that relates the feature value analysis result to each portion of heart (Sato, paragraph 44, lines 1 – 5; Tables 4 and 5).

Regarding claim 7, Sato discloses the feature value is based on the constituent

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elements of an ECG including P wave, Q wave, R wave, S wave, ST segment, or T wave (Sato, paragraph 3, lines 3 – 4; paragraph 4, lines 5 – 8).

Regarding claim 8, Sato discloses the disease information determining means determines the disease information based on the Minnesota code as an ECG classification reference (Sato, paragraph 30, lines 1 – 5).

Regarding claim 9, Sato discloses outputting heartbeat-related information by sound and/or varying display style during analyzing the ECG (Sato, paragraph 51, lines 1 – 3).

Regarding claim 15, Sato discloses a method for analyzing an ECG comprising the step of analyzing the ECG by combining an algorithm for analyzing level of an ECG feature value and an algorithm for determining whether a patient's cardiac function is abnormal, which is based on information including the feature value (Sato, paragraph 27, lines 1 – 3; paragraph 30, lines 1 – 7).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sato as applied to claims 1 and 3 above in view of Masuda et al. (U.S. Patent 6,322,516) and Albrecht et al. (U.S. Patent 6,047,206).

The patent issued to Masuda discloses using a chart in a radar chart form to display abnormalities in blood pressure. The patent issued to Albrecht discloses localizing cardiac measurements.

Regarding claim 4, both Masuda and Albrecht fail to disclose outputting means further displays the chart in a radar chart form that arranges each of the feature value analysis result at the corresponding portion of the heart. However, Masuda discloses a radar chart representing a blood pressure value, a pulse period, and a pulse area (Masuda, column 12, lines 4 – 11). Albrecht discloses displaying cardiac measures in different areas that correspond to areas of the body surface (Albrecht, column 4, lines 13 – 23).

It would have been obvious to one having ordinary skill at the time the invention was made to have modified the display of the different portions of the heart, as taught by Albrecht, to include a radar chart, as taught by Masuda, since both involve obtaining and analyzing physiological information related to the patient's heart, and thus the references are analogous art. It also would have been obvious to combine the teachings of Albrecht and Masuda with those of Sato since Sato discloses an apparatus

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for recording and analyzing cardiac potential, and thus is analogous art with Albrecht and Masuda.

8. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato as applied to claims 1 and 3 above, and further in view of the English translation of Dainippon Pharmaceutical Co. (Japanese Patent 2001-8914).

The patent issued to Dainippon Pharmaceutical Co. discloses extracting values from cardiograms and displaying the values to evaluate heart function.

Regarding claims 5 and 6, Dainippon Pharmaceutical Co. discloses outputting history of the feature value analysis result and/or history of the disease information result, and history summary when outputting the feature value analysis result (Dainippon, paragraph 13, lines 1 – 6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Sato to include displaying the history and the history summary, as taught by Dainippon, since both references deal with obtaining, analyzing, and displaying ECG waveforms, and thus the references are analogous art.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sato as applied to claim 1 above in view of Patton et al. (U.S. Patent 4,989,610).

The patent issued to Patton discloses a method and system of ECG data review and analysis.

Regarding claim 9, Patton discloses outputting heartbeat-related information by sound and/or varying display style during analyzing the ECG (Patton, column 45, lines

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37 – 39).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Sato to include presenting the sounds of detected heart beats simultaneously with the ECG display, as taught by Patton, since both references disclose methods of ECG analysis, and thus the references are analogous art.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sato as applied to claim 1 above in view of Donehoo et al. (U.S. Patent 5,788,644).

The patent issued to Donehoo discloses a multi-lead ECG monitor.

Regarding claim 10, Donehoo discloses outputting a warning signal when the analysis cannot be executed during analyzing the ECG (Donehoo, column 3, lines 64 – 66).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Sato to include an alarm as taught by Donehoo, since both references teach methods of analyzing ECG signals, and thus the references are analogous art.

11. Claim 13 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sato.

Regarding claim 13, Sato discloses a method for analyzing an ECG comprising the steps of: analyzing magnitude of an ECG feature value (Sato, paragraph 8, lines 3 – 6); determining disease information relating to a patient's disease based on information including the feature value (Sato, paragraph 30, lines 1 – 5); and outputting the



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narrowed disease information result candidates (Sato, paragraph 19, lines 2 – 4; paragraph 30, lines 1 – 5). Sato, however, fails to disclose narrowing down the candidates of disease information result based on the feature value analysis result.

In order to display/output the disease information result, as taught by Sato, the information would have to have been narrowed down in order to determine the correct output. Therefore, it is the examiner's belief that narrowing down the candidates of disease information result is an inherent feature of determining disease information. If it were possible to determine the disease information in a different way, it would then be obvious to narrow down the candidates of disease information in order to arrive at the best disease information result for output. Due to this, examiner shifts burden of proof to applicant as in *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112- 2112.02.

12. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sato, in view of the partial English translation of Fujitsu Ltd. (Japanese Patent 55-69896).

The patent issued to Fujitsu Ltd. discloses a method of analyzing ECG waveforms and classifying a disease associated with that waveform.

Regarding claim 14, Sato discloses a method for analyzing an ECG comprising the steps of: analyzing magnitude of an ECG feature value (Sato, paragraph 8, lines 3 – 6); determining disease information relating to a patient's disease based on information including the feature value (Sato, paragraph 30, lines 1 – 5); and outputting the disease information result (Sato, paragraph 30, lines 1 – 5). Sato fails to disclose determining different disease information than the determined disease information by considering

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both the feature analysis result and the determined disease information result.

However, Fujitsu Ltd. discloses obtaining data from both the analysis data for the electrocardiographic waves and the Minnesota code, and then displaying it (Fujitsu, page 4, line 20 – page 5, line 6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Sato and Fujitsu Ltd. since both teach obtaining and analyzing ECG waveforms, and thus, the references are analogous art.

### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Dietrich whose telephone number is 571-270-1895. The examiner can normally be reached on Mon - Fri, 8:00AM - 5:00PM, Alt Fri, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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